GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:72
ANSWERED ON:22.10.2008
NON REPORTING OF MEDICINAL SIDE EFFECTS TO WHO
Muqueem Shri Mohammed;Yaskhi Shri Madhu Goud

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether India has not reported a single instance of medicinal side-effects from drugs during the last three years to an international drug monitoring database set up by the World Health Organization (WHO) as reported in the 'Mint' dated 28 July, 2008;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Drug Controller General of India (DCGI) puts a condition of Pre-Market Surveillance Studies (PMS) on the new drugs' approval;

(d) if so, the details thereof including the names of companies which have not submitted the PMS data; and

(e) the corrective measures taken/being taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 72 FOR 22ND OCTOBER, 2008

(a)&(b): Yes, Sir.
India has not reported Adverse Drug Reactions (ADRs) to the WHO Uppsala monitoring system during the period 2005 to 2007 because of the software and the attendant fees issue. However, now a decision has been taken to link the Indian Pharmacovigilance data with the WHO sponsored Uppsala system.

(c) Pre-Marketing Surveillance (PMS) Study is not required to be submitted during the process of approval of new drugs. However, Phase-I, II and III clinical trials data in accordance with the requirement of Schedule Y of the Drugs and Cosmetics Rules are taken into consideration.

(d)&(e): Do not arise.